

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
10 March 2005 (10.03.2005)

PCT

(10) International Publication Number
WO 2005/021800 A3

(51) International Patent Classification⁷: **C12Q 1/68**

(21) International Application Number:
PCT/US2004/026857

(22) International Filing Date: 17 August 2004 (17.08.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/497,222 22 August 2003 (22.08.2003) US
60/543,784 11 February 2004 (11.02.2004) US

(71) Applicant (for all designated States except US): SIMA
THERAPEUTICS, INC. [US/US]; 2950 Wilderness
Place, Boulder, CO 80301 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): RADKA, Susan

[US/US]; 7933 Orion Way, Arvada, CO 80007 (US).
ZINNEN, Shawn [US/US]; 2378 Birch Street, Denver,
CO 80207 (US). JADHAV, Vasant [IN/US]; 1951 Grand-
view Avenue, Aptment #A4-B, Boulder, CO 80302 (US).
MCSWIGGEN, James [US/US]; 4866 Franklin Drive,
Boulder, CO 80301 (US). VAISH, Narendra, K. [IN/US];
1313 Williams Street, #503, Denver, CO 80218 (US).

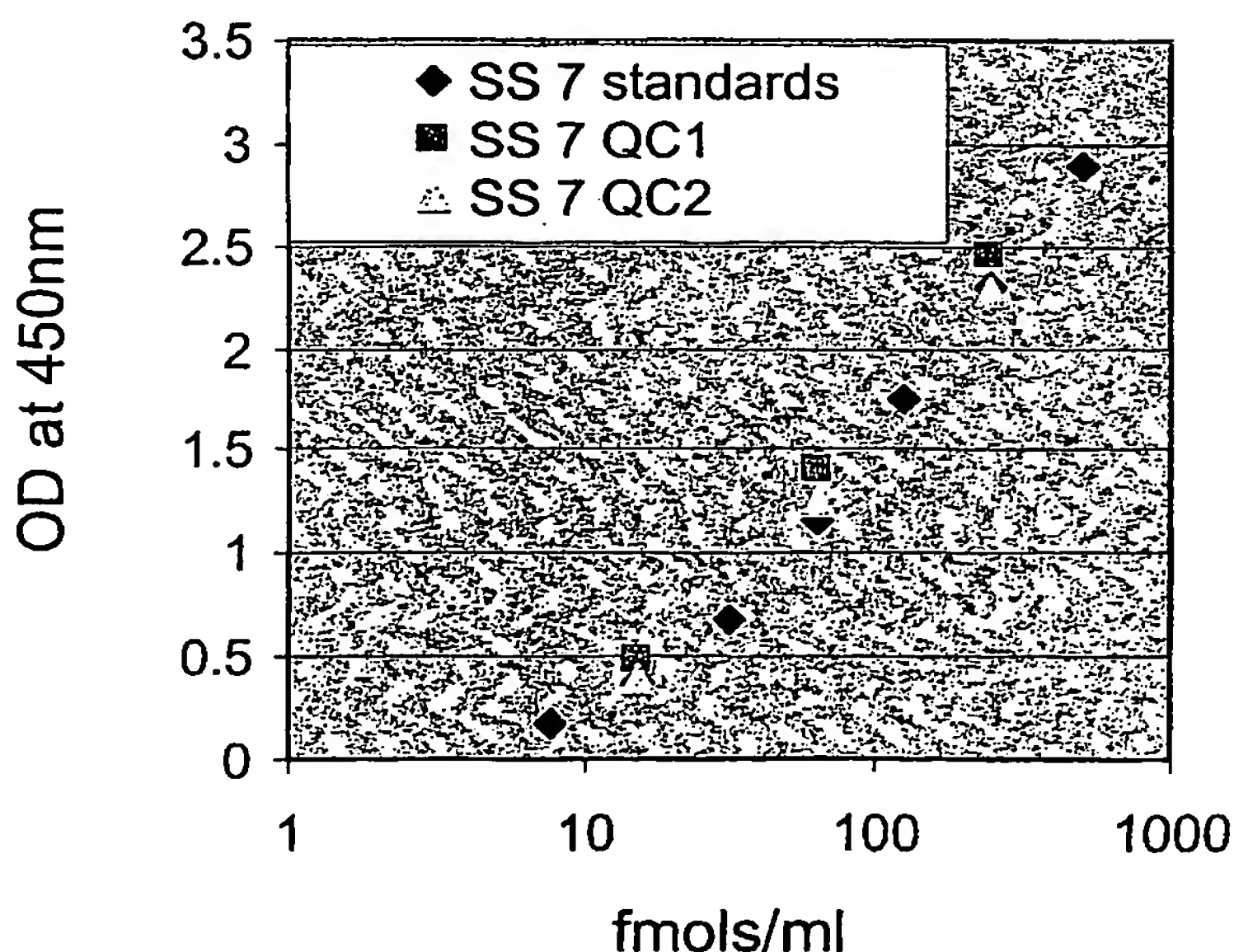
(74) Agent: GREENFIELD, Michael, S.; McDonnell
Boehnen Hulbert & Berghoff LLP, 300 South Wacker
Drive, Suite 3100, Chicago, IL 60606 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

[Continued on next page]

(54) Title: DETECTION AND QUANTITATION OF NUCLEIC ACID MOLECULES IN BIOLOGICAL SAMPLES

siNA Stab 7 Single Stranded Quality Control Sample



(57) Abstract: The present invention concerns processes for the detection and quantitation of nucleic acid molecules, polynucleotides, and/or oligonucleotides in a sample using hybridization-detection assays, antibody-mediated recognition assays, nucleic acid sensor molecules, chromatographic assays, and/or electrophoresis assays. The present invention specifically concerns processes for the detection and quantitation of double stranded nucleic acid molecules, polynucleotides, and/or oligonucleotides in a sample using hybridization-detection assays. The nucleic acid molecules, polynucleotides, and/or oligonucleotides can include molecules that mediate RNA interference, such as short interfering nucleic acid (siNA), short interfering RNA (siRNA), double-stranded RNA (dsRNA), micro-RNA (miRNA), and short hairpin RNA (shRNA) molecules. The nucleic acid molecules, polynucleotides, and/or oligonucleotides can include nucleic acid aptamers, enzymatic nucleic acid

molecules, decoys, antisense, 2',5'-oligoadenylate molecules, triplex forming oligonucleotides or any other nucleic acid molecule of interest. The present invention also concerns kits that allow for the detection and quantitation of nucleic acid molecules, polynucleotides, and/or oligonucleotides in a sample.



(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) **Date of publication of the international search report:**

21 April 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.